

The Administrative Procedure Act requires the publication of substantive policy statements by agencies (A.R.S. § 41-1013(B)(14)). Substantive policy statements are written expressions which inform the general public of an agency's current approach to rule or regulation practice. Substantive policy statements are advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that a substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under A.R.S. § 41-1033 for a review of the statement.

## NOTICE OF SUBSTANTIVE POLICY STATEMENT

### ARIZONA RADIATION REGULATORY AGENCY

[RAM 36]

- 1. Subject of the substantive policy statement and the substantive policy statement number by which the policy statement is referenced:**  
Radiopharmaceuticals for Human Use
- 2. Date the substantive policy statement was issued and the effective date of the policy statement if different from the issuance date:**  
Effective February 10, 1997
- 3. Summary of the contents of the substantive policy statement:**  
Grants New Drug Application equivalency to biological products which have received a Product License Approval.
- 4. A statement as to whether the substantive policy is a new statement or a revision:**  
This is a current policy statement.
- 5. The agency contact person who can answer questions about this substantive policy statement:**  
Name: Brian Goretzki, Program Manager, RAM  
Address: Arizona Radiation Regulatory Agency  
4814 South 40<sup>th</sup> Street  
Phoenix, AZ 85040  
Telephone: (602) 255-4845, ext. 234

AUG 01 2012

  
APPROVED BY (DIRECTOR)

DATE